Section 10: Executive Summary

K053100

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Device Information:

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle. Suite 150 Danville, CA 94506 Tel: 925-648-3500
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Electrosurgical Probe
Device Classification & Code:	Class II, GEI (21 CFR 870.4420)
Device Classification Name:	Electrosurgical cutting and coagulation device and accessories
Device Proprietary Name:	Estech Cobra Bipolar System

Predicate Device Information:

Predicate Devices:	Cobra Bipolar System (K023288)
Predicate Device Manufacturers:	Boston Scientific
Predicate Device Common Name:	Electrosurgical Probe
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification & Code:	Class II, GEI

b. Date Summary Prepared
October 31, 2005

c. Description of Device
The Estech Cobra Bipolar System is identical to the Boston Scientific Cobra Bipolar System.

Both Bipolar Systems are comprised of two components: a reusable surgical clamp an associated coagulating device known as the Cobra Bipolar Insert. The Bipolar Insert is a sterile, single use device that transmits radiofrequency (RF) energy to coagulate soft tissues and fits in a jaw of the clamp. The Bipolar System will be used with the Boston Scientific Cobra Electrosurgical Unit (ESU). The ESU delivers 460 kHz of RF energy to selected Bipolar Insert electrodes, modulates the RF energy to keep all selected Bipolar Insert electrodes' temperatures essentially the same, and adjusts the power output to maintain the maximum temperature of all selected electrodes close to the set point.

d. Intended Use

The ESTECH Cobra Bipolar System is intended for the coagulation of soft tissue during general surgery. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

e. Comparison to Predicate Device

The Estech Cobra Bipolar System is identical in intended use, technology, design, materials, manufacture, packaging and sterilization to the predicate Boston Scientific Cobra Bipolar System.

This 510(k) is being filed to transfer sales and responsibility of this portion of Boston Scientifics' product line over to Estech. For the time being Boston Scientific will continue to manufacture the device. Estech will add additional contract manufacturers as needed.

Estech concludes that the Estech Cobra Bipolar System is substantially equivalent to the Boston Scientific Cobra Bipolar System.

f. Summary of Supporting Data

Supporting data is not necessary to support this submission since the Estech Cobra Bipolar System is identical to the predicate device, the Boston Scientific Cobra Bipolar System (K023288).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2005

Endoscopic Technologies, Inc.
% Mr. Craig Coombs
President
Coombs Medical Device Consulting
1193 Sherman Street
Alameda, California 94501

Re: K053100
Trade/Device Name: Estech Cobra Bipolar System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and Coagulation device and accessories.
Regulatory Class: II
Product Code: GEI
Dated: November 2, 2005
Received: November 8, 2005

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K053100

Device Name: ESTECH Cobra Bipolar System

Indications For Use:

The ESTECH Cobra Bipolar System is intended for the coagulation of soft tissue during general surgery. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mechy D for MKM

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K053100